

Patent Application of Joar Opheim
Flavored Gelatin Capsule and Method of Manufacture

4 This application is a continuation of my co-pending application 09/416,017
5 filed on October 6, 1999, and the entire disclosure thereof is hereby
6 incorporated herein by reference. *[Handwritten mark]*

reference.
now US pat. # 6,346,231

BACKGROUND OF THE INVENTION

10 1. Field of the Invention

This invention relates to capsule formulations, medicinal and nutritive dose encapsulations and methods of manufacture of capsules. More specifically, the invention introduces flavoring into the manufacture of capsules and encapsulated doses.

17 2. Conventional Art

The taste of many medicinal and nutritive components can be quite distinctive and potentially unpleasant. Improvements in the taste of certain drugs and nutritional supplements can lead to a higher compliance by consumers. A higher compliance will result in greater commercial success for the drug and supplement manufacture and in increased health and well being particular consumers.

Taste is both a matter of purely subjective preference. Yet human taste is also strongly influenced by experience and cultural impressions. Broad generalizations about consumer taste presence can thus sometimes be relied upon in predicting market acceptance of specific drug and nutritive formulations. In Norway, for example the tastes of fish oils are far more palatable than in the United States. As a consequence of this United States market aversion to the taste of fish oils, many residents of the United States are less willing to ingest fish oils and will therefore not benefit from the nutritional and medicinal qualities of fish oils.

36 Yet the composition of certain fish oils includes elements that are

1 identified in medical literature as providing significant health benefits.
2 Polyunsaturated fatty acids, to include long chain Omega 3 fatty acids such
3 as eicosapentenoic acid (EPA) and docosahexenoic acid (DHA) are present
4 in the livers of lean fish and other tissues of
5 fatty fish. The human body cannot synthesize these fatty acids nor can it
6 derive them from other fatty acids. As these fatty acids provide both
7 medicinal and nutritional benefits, an intake of up two grams per day has
8 been recommended by certain medical authorities.

9

10 It is suspected that Eicosanoids derived from EPA might have an anti-
11 inflammatory effect on humans. It has been suggested that EPA might
12 decrease blood levels of TG lipids, increase blood levels of high density
13 lipids (HDL), decrease blood clotting, reduce the incidence of cardiac
14 arrhythmia and stabilize heart rhythm.

15

16 It has been suggested that DHA may also decrease blood levels of TG
17 lipids, increases blood levels of high density lipids (HDL). Furthermore,
18 DHA might lower blood pressure, attack early phases of inflammation,
19 facilitate the growth, development and function of the central nervous
20 system and improves the clinical symptoms of depression and
21 schizophrenia.

22

23 Increasing the consumption of recommended doses of certain Omega-
24 3 fatty acids might therefore have a medically and nutritionally beneficial
25 affect on many consumers and patients. Yet conventional techniques to
26 improve the palatability of fish oils and other subjectively harsh tasting
27 substances are limited in the prior art to the addition of flavorings into a
28 mixture of the substances themselves. The flavoring of capsules of
29 encapsulated formulations has been absent in the conventional art.

30

31 **OBJECTS OF THE INVENTION**

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33 It is therefore an object of the present invention to provide a method of
34 manufacture of gelatin capsules.

35 It is another object of the present invention to provide a gelatin
36 capsule comprising a flavor.

1 It is an additional object of the present invention to optionally provide
2 a flavored gelatin capsule containing a fish oil.

3 It is an yet another object of the present invention to optionally
4 provide a flavored gelatin capsule containing a flavored fish oil.
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6

7 SUMMARY OF THE INVENTION 8

9 These and other objects and advantages of the present invention are
10 achieved by providing a flavored gelatin capsule comprising a water soluble
11 flavor. The flavored gelatin capsule may include about 10 to about 70 parts
12 by weight of a gelatin, about 10 to about 35 parts by weight of a glycerol,
13 about 8 to about 35 parts by weight of a moisturizer and about 1 parts by
14 weight of the water soluble flavoring. The flavoring of the capsule improves
15 the taste and palatability of the capsule and will subjectively improve the
16 taste of the gelatin and a dose or contents contained within the flavored
17 gelatin capsule to individual consumers or patients.
18

19 The flavor may be one of, or a combination of suitable flavors known
20 in the art, to include berry, strawberry, chocolate, cocoa, vanilla, lemon, nut,
21 almond, cashew, macadamia nut, coconut, blueberry, blackberry, raspberry,
22 peach, lemon, lime, mint, peppermint, orange, banana, chili pepper, pepper,
23 cinnamon, and pineapple.
24

25 The gelatin capsule composition may include a polyol, such as
26 sorbitol, glycerol or other suitable softening agent known in the art.
27

28 A preferred embodiment of the present invention includes flavoring
29 the contents of the gelatin capsule in addition to flavoring the gelatin
30 capsule. In particular, an oil soluble flavoring may be optionally mixed with
31 a fish oil that is encapsulated within the capsule. The oil soluble flavoring
32 may be similar to the taste of the flavor of the capsule, e.g., strawberry and
33 strawberry, or the taste of the oil flavoring may be complementary to the
34 capsule flavoring, e.g., banana and strawberry.
35

36 Fish oil containing Omega 3 fatty acids such as eicosapentenoic acid

1 (EPA) and docosahexenoic acid (DHA) are one appropriate subject of
2 inclusion into certain preferred embodiments of the present invention. The
3 capsule of these certain preferred embodiments is flavored and the fish oil
4 may optionally be flavored.

5
6 The method of the present invention includes the manufacturing
7 process steps of combining gelatin, a glycerol or a polyol like sorbitol as a
8 softener, water or a moisturizer containing water, a flavoring agent and
9 optionally a coloring agent such as a titanium oxide, keratin or other suitable
10 coloring agent known in the art.

11
12 Modified vegetable starch is substituted for gelatin in certain preferred
13 embodiments of the present invention. Where gelatin is used, the gelatin
14 may be a suitable mammalian or fish gelatin known in the art. The suitable
15 gelatin or vegetable starch selected is used as a principal forming agent of
16 the capsule.

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19 **BRIEF DESCRIPTION OF DRAWINGS**

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21 FIG. 1 is a flavored gelatin capsule containing a fish oil dose.

22 FIG. 2 is manufacturing process flow chart illustrating an embodiment
23 of the method of the present invention.

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26 **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

27
28 In describing the preferred embodiments, certain terminology will be
29 utilized for the sake of clarity. Such terminology is intended to encompass
30 the recited embodiment, as well as all technical equivalents which operate in
31 a similar manner for a similar purpose to achieve a similar result.

32
33 Referring now to Figure 1, an encapsulated composition of a gelatin
34 capsule and fish oil 2, or fish oil capsule 2, is formed by the encapsulation of
35 a dose of fish oil 6 by a gelatin capsule 4. The gelatin capsule 4 is made of
36 gelatin, glycerol, water, a flavoring and optionally a coloring agent. The fish

1 oil dose 6 includes 180 mg of EPA and 120 mg of DHA.

2

3 Referring now to Figure 1 and 2, the manufacturing process of the
4 preferred embodiment 2 of includes the steps of combining gelwatch
5 ingredients, melting and forming a liquefied gelwatch, delivering the
6 liquefied gelwatch and the fish oil 6 to an encapsulation machine,
7 encapsulating a dose of fish oil, drying the encapsulated dose, washing the
8 encapsulated dose and packaging the fish oil capsules 2 for shipment.

9

10 The gelwatch ingredients may include gelatin or a gelatin substitute
11 such as modified starch or other suitable gelatin substitute known in the art,
12 a softener such as glycerol or sorbitol or other suitable polyol or other gelatin
13 softener known in the art, a flavoring agent such as strawberry flavor
14 Firmenich #52311A or other suitable gelatin capsule flavoring known in the
15 art and optionally a coloring agent such as keratin or other suitable gelatin
16 capsule coloring agent known in the art.

17

18 The preferred embodiment 2 may be formed from a gelwatch mixture
19 of 45 parts by weight of gelatin, 20 parts by weight of glycerol, 35 parts by
20 weight of water and 0.5 or more parts by weight of strawberry flavor
21 Firmenich #52311A. The gelwatch ingredients are then heated to about 60
22 degrees to 70 degrees Celsius and mixed together. The capsule is made of
23 the gelwatch material. The liquefied gelwatch and the fish oil 6 is then
24 poured into an encapsulation machine. The encapsulation machine then
25 forms the fish oil capsule 2 comprising the fish oil dose 6 encapsulated by
26 the gelatin capsule 4.

27

28 In certain alternate preferred embodiments of the present invention the
29 range of water parts initially combined with the gelwatch may range from
30 about 10 parts by weight to about 45 parts by weight; the amount of gelatin
31 initially combined into the gelwatch may range from 10 parts by weight to
32 about 70 parts by weight; and the amount of glycerol or other suitable
33 softener known in the art may range from about 10 parts by weight to about
34 35 parts by weight.

35

36 The capsule composition 2 comprises about 500 milligrams of the fish

1 oil dose 6 and about 240 milligrams of capsule 4 as formed from the
2 gelwatch.

3
4 The fish oil capsule composition 2 is then dried at a temperature of
5 about 20 degrees Celsius. The water content of the gelatin capsule is
6 reduced to about 8% +/- 2% by evaporation during the drying process step.
7 The capsule 2 is then washed and packaged for shipment.

8
9 Experimental testing of the effects of varying amounts of the flavoring
10 in both the capsule 4 and the fish oil 6 has shown that a concentration of
11 0.5% in the fish oil 6 of the Firmenich #52311A flavor will degrade in less
12 than a year's span to below a desirable level of potency to the average North
13 American consumer. Levels of 1 part by weight are preferred in order to
14 extend the effective shelf life of the composition 2 beyond one year.

15
16 In addition, stream of commerce testing of concentration levels of
17 Firmenich #52311A has shown that a level in excess of about 1.0 part by
18 weight of the Firmenich #52311A in the capsule 4 provides an unexpected
19 increase in the palatability of the composition 2 by generating a flavored
20 bouquet from the capsules 2, whereby the consumer is greatly encouraged to
21 ingest the composition 4 in a favorable response to his or her olfactory
22 appreciation of the bouquet.

23
24 Certain preferred embodiments comprise fish oil presenting
25 concentrations of Omega 3 fish as high or higher than 80% of the total
26 weight of the dose 6, wherein the fish oil may include 50% DHA of the total
27 weight of the dose 6, 20% EPA of the total weight of the dose 6 and about
28 10% by weight of other Omega 3 compounds. The concentration levels of
29 the flavoring additive of a fish oil dose may, in certain preferred
30 embodiments of the present invention having about 80% by weight of
31 Omega 3 components, is reduced to from about 0.25% by weight to about
32 0.50% by weight of the dose 6

33
34 Those skilled in the art will appreciate that various adaptations and
35 modifications of the just-described preferred embodiments can be
36 configured without departing from the scope and spirit of the invention.

1 Therefore, it is to be understood that, within the scope of the appended
2 claims, the invention may be practiced other than as specifically described
3 herein.